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PATENT COOPERATION TREATY

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From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

GlaxoSmithKline	
Corporate IP	
Received BRENTFORD	
15 OCT 2004	
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JRM: N/A	ON: UPDATED ON:
ATTY CHECKED: [initials]	

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT

(PCT Rule 71.1)

To:

Giddings, Peter John
GLAXOSMITHKLINE
Corporate Intell. Property
(CN925.1)
980 Great West Road
Brentford, Middlesex TW8 9GS
GRANDE BRETAGNE

Date of mailing
(day/month/year)

12.10.2004

Applicant's or agent's file reference
JNR/PG4902

IMPORTANT NOTIFICATION

International application No.
PCT/EP 03/08497

International filing date (day/month/year)
30.07.2003

Priority date (day/month/year)
01.08.2002

Applicant

GLAXO GROUP LIMITED et al.

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

Name and mailing address of the international
preliminary examining authority:



European Patent Office
D-80298 Munich
Tel. +49 89 2399 - 0 Tx: 523656 epmu d
Fax: +49 89 2399 - 4465

Authorized Officer

Zibell, M

Tel. +49 89 2399-7213



PATENT COOPERATION TREATY

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference JNR/PG4902	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA416)	
International application No. PCT/EP 03/08497	International filing date (<i>day/month/year</i>) 30.07.2003	Priority date (<i>day/month/year</i>) 01.08.2002
International Patent Classification (IPC) or both national classification and IPC B05B11/00		
Applicant GLAXO GROUP LIMITED et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 7 sheets, including this cover sheet.
- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).
- These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:
- I ☒ Basis of the opinion
 - II ☐ Priority
 - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
 - IV ☐ Lack of unity of invention
 - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
 - VI ☐ Certain documents cited
 - VII ☐ Certain defects in the international application
 - VIII ☐ Certain observations on the international application

Date of submission of the demand 12.02.2004	Date of completion of this report 12.10.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer Thanbichler, P Telephone No. +49 89 2399-8957 <div style="text-align: right;">  </div>

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. **PCT/EP 03/08497**

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-29 as originally filed

Claims, Numbers

1-50 as originally filed

Drawings, Sheets

1/4-4/4 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

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5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos. 37-47

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 37 are so unclear that no meaningful opinion could be formed (*specify*):

see separate sheet

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☐ no international search report has been established for the said claims Nos.

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the Standard.

☐ the computer readable form has not been furnished or does not comply with the Standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	33-36
	No: Claims	1-32
Inventive step (IS)	Yes: Claims	33-36
	No: Claims	1-32
Industrial applicability (IA)	Yes: Claims	1-36
	No: Claims	-

2. Citations and explanations

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Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: US 2002/008122 A (GREINER-PERTH JUERGEN ET AL) 24 January 2002 (2002-01-24)
D2: DE 196 10 456 A (PFEIFFER ERICH GMBH & CO KG) 18 September 1997 (1997-09-18)
D3: WO 00/18458 A (ANDERSON GREGOR JOHN MCLENNAN ;RAND PAUL KENNETH (GB); GLAXO GROUP) 6 April 2000 (2000-04-06)

INDEPENDENT CLAIM 1

The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claim 1 is not new in the sense of Article 33(2) PCT.

The document D1 discloses (the references in parentheses applying to this document):

A fluid dispensing device for spraying a fluid into a body cavity comprising a housing, a nozzle for insertion into a body cavity, a fluid discharge device moveably housed within the housing, the fluid discharge device comprising a container for storing the fluid to be dispensed (fig. 4a) and a compression pump having a suction inlet located within the container and a discharge outlet at one end of the container for transferring fluid from the pump to the nozzle and a finger operable means to apply a force to the container to move the container towards the nozzle so as to actuate the pump wherein the finger operable means comprises of at least one lever pivotally supported within the housing and driveably connected to the container so as to urge the container towards the nozzle when the or each lever is actuated by a user (figs.4, 6; claim 1; par. [0052-0057].

INDEPENDENT CLAIM 33

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None of the cited documents show a toothed rack attached to the container.
Therefore claim 33 seem to fulfill the requirement of Art. 33(2) PCT with respect to novelty.

INDEPENDENT CLAIM 37

No assessment of novelty and inventive step can be made by the Examining Division, because claim 37 is unclear for the following reasons:

1. The formulation "...for a fluid discharge device..." is only facultative and is not limiting the claim and is therefore not necessarily included in the scope of the claim (C-III-4.6).
2. A container is disclosed which is defined by a fluid discharge device (...which is not within the scope of the claim; see point 1. above)
3. The formulation "... a body having a nozzle extending therefrom for insertion into a body cavity..." is not clear. The word "body" can be read as one or two different entities.

DEPENDENT CLAIMS

The following dependent claims do not appear to contain any additional features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT with respect to novelty and/or inventive step, the reasons being as follows:

- Claim 2: see D2 claim 1; fig. 8
Claim 3: see D2 claim 1; fig. 8
Claim 14: see D1 fig. 2; D2 figs. 1-3
Claim 15: see D1 fig. 2; D2 figs. 1-3
Claim 20: see D1 figs. 4a, 5a, b par. [0054-0056]
Claim 21: see D1 fig. 4a
Claim 22: see D1 fig. 4a
Claim 23: see D1 fig. 4a
Claim 24: see D1 fig. 4a
Claim 25: see D1 fig. 4a
Claim 26: see D1 par. [0003]

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FURTHER REMARKS

Independent claims are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

Claims 48-50 contain references to the description and the drawings. According to Rule 6.2(a) PCT, claims should not contain such references except where absolutely necessary, which is not the case here.

Contrary to the requirements of Rule 5 PCT the documents D1-D3 are not included in the description.